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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61C 5/14	A1	(11) International Publication Number: WO 92/03983
		(43) International Publication Date: 19 March 1992 (19.03.92)

(21) International Application Number: PCT/US91/05820

(22) International Filing Date: 14 August 1991 (14.08.91)

(30) Priority data:
578,150 6 September 1990 (06.09.90) US

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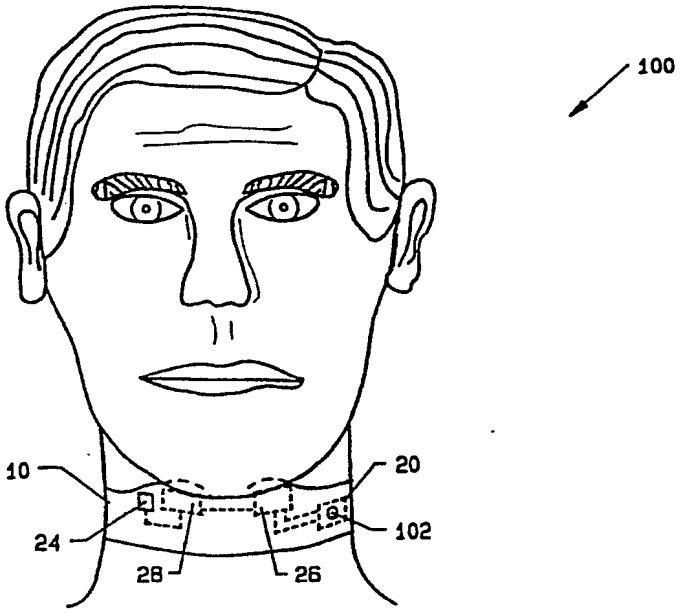
(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

Published
With international search report.

(54) Title: OBSTRUCTIVE SLEEP APNEA COLLAR



(57) Abstract

A system for the treatment of obstructive sleep apnea packaged in a collar (10) which can be worn by a patient without any special preparation. The collar (10) has an adjustable attachment means, such as hook (14) and latch (16), to accommodate variations in neck size. The collar (10) is properly oriented using variations in physical shape and/or color. An optional feedback system permits the patient to readily verify proper orientation. The collar (10) contains at least one sensor (24) to monitor functioning of the respiratory system of the patient. Suitable parameters to be sensed include breath or snoring sounds, breath temperature, air flow, blood gases via either direct or indirect means, motion of the chest, circumference of the chest, expansion of the chest, resistance of the airway via either direct or indirect means, and expansion of the neck. Preferably, the sensor (24) is properly positioned directly with attachment of the collar.

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OBSTRUCTIVE SLEEP APNEA COLLAR

CROSS REFERENCE TO CO-PENDING APPLICATIONS

None.

BACKGROUND OF THE INVENTION

1. Field of the Invention - The present invention relates generally to medical devices, and more particularly, relates to transcutaneous electrical stimulation treatment of obstructive sleep apnea.

2. Description of the Prior Art - Sleep apnea is a medical condition which effects a large segment of the population. It exists in several forms. Perhaps the most dangerous, called central apnea, is associated with a lack of central drive to breath or with a disruption of the neural pathways from the brain to the diaphragm muscles. Research has been progressing for some time with one mode of treatment being electrical stimulation of the phrenetic nerve, thereby controlling function of the diaphragm. William W. L. Glenn describes the nature of this research in "Diaphragm Pacing: Present Status" in Pace, Volume 1, pages 357 - 370, July - September 1978.

A second form of sleep apnea, and of most concern to the present invention, is that which obstructs the upper air passageways. This condition has numerous deleterious results including disturbance of the patient and sleep partner and loss of effectiveness of the sleep process resulting in excessive patient fatigue. Long term effects include hypertension and cardiac problems.

The simplest forms of treatment for upper air passage obstructive sleep apnea involve mechanical constraints. U.S. Patent No. 4,304.227 issued to Samelson describes such a device. Various surgical techniques are also employed including tracheostomy.

Perhaps the most common technique is through the use of systems which detect the obstructive condition and alert the patient to the problem in some fashion. Examples of this type of system include: U.S. Patent No. 2,999,232 issued to Wilson; U.S. Patent No. 3,032,029 issued to Cunningham; U.S. Patent No. 3,480,010 issued to Crossley; U.S. Patent No. 3,593,703 issued to Gunn et al.; U.S. Patent No. 3,696,377 issued to Wall; U.S. Patent No. 3,998.209 issued to Macvaugh; U.S. Patent No. 4,220,142 issued to Rosen et al.; and U.S. Patent No. 4,593,686 issued to Lloyd et al. These devices employ a variety of techniques, but each tends to be based upon detection of the condition and producing an alarm. Unfortunately, the alarm may rouse the patient to the extent that patient's sleep is disturbed, thereby exacerbating the very problem caused by the apnea episode.

Recently, research has been conducted which shows that the obstruction within the upper air passageway may be cleared with electrical stimulation. Two articles, herein incorporated by reference, describing this research may be found in American Review of Respiratory Disease Volume 140, 1989 at pages 1279 through 1289. The first article is "Effects of Electrical Stimulation of the Genioglossus on Upper

Airway Resistance in Anesthetized Dogs", by Hiroshi Miki et al. The second article is "Effects of Submental Electrical Stimulation during Sleep on Upper Airway Patency in Patients with Obstructive Sleep Apnea", also by Hiroshi Miki et al.

U.S. Patent No. 4,830,008 issued to Meer discusses an implantable system for treatment of obstructive sleep apnea using electrical stimulation. The implanted sensor(s) are used to sense inspiratory effort and stimulate the nerves of the upper airway in synchrony with the respiration cycle. Because upper airway stimulation may not be required for each inspiratory effort, Meer proposes an embodiment which also senses muscular activity in the upper airway to inhibit stimulation for certain respiratory cycles. However, it is not clear that the added complexity and morbidity of an implantable system are justified in the absence of evidence that stimulation only during the inspiratory effort is either necessary or sufficient.

SUMMARY OF THE INVENTION

The present invention overcomes the disadvantages of the prior art systems by providing an external device for the effective treatment of obstructive sleep apnea using a collar which may be easily and properly attached by the patient. The collar senses the onset of an apnea episode and automatically applies electrical signals which either stimulates the patient's muscles to clear the obstruction or stimulates a reflexive response of causing the patient's muscles to clear the obstruction. Because the device is worn externally, it does not require the expense and risk associated with an implant procedure. Because the electrical stimulation is supplied with little sensation, the effectiveness of sleep is preserved.

The collar is readily attachable using hook and latch or other suitable fasteners. Means located on the collar ensure proper placement of the sensor and stimulation electrodes. The positioning means can take the form of variations in shape or color of the collar. The collar is self contained; and therefore, promotes patient compliance through ease of use. It may be made in disposable form to ensure ease of manufacture.

A sensor located on or near the collar is used to determine the onset of an apnea episode. Proper functioning of the respiratory system may be monitored directly in the form of air flow, direct or indirect blood gas measurements (such as pulse oxygen saturation), or indirectly via breath or snoring

sounds, breath temperature, pressure sensors, thoracic impedance, strain gauges, or airway resistance. The output of the sensor is conditioned and interpreted, and used to determine whenever an apnea event is initiated. A stimulation signal is generated which is coupled to transcutaneous neuro muscular electrodes. These stimulation signals cause the genioglossus and related muscle groups to contract thereby clearing the upper air passageway.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects of the present invention and many of the attendant advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

FIG. 1 is a plan view of an obstructive sleep apnea collar;

FIG. 2 is an obstructive sleep apnea collar showing an alternative positioning means;

FIG. 3 is an obstructive sleep apnea collar showing a second alternative positioning means;

FIG. 4 is a frontal view of a patient wearing an obstructive sleep apnea collar;

FIG. 5 is a side view of a patient wearing an obstructive sleep apnea collar;

FIG. 6 is an overall view of the electronic module of the obstructive sleep apnea collar; and,

FIG. 7 is a block diagram of the electronic circuit of the obstructive sleep apnea collar.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 is a plan view of an obstructive sleep apnea collar 10 of the present invention. The main substrate 12 is of a flexible material suitable for wrapping about the patient's neck. Preferably main substrate 12 is of a porous woven material which permits the collar to "breathe". Main substrate 12 is fastened about the neck of the patient using convenient fasteners such as hook 14 and latch 16 (see also FIGS. 4 and 5). Preferably, hook 14 and latch 16 are sufficiently wide to permit adjustment to necks of varying sizes.

It is important that collar 10 be properly positioned when attached to the neck of the patient to ensure that the components located on main substrate 12 are properly positioned. In the preferred embodiment, this is accomplished with chin notch 18 which accommodates the chin of the patient. In this way, the patient can easily feel that collar 10 is properly positioned.

Sensor 24 is used to determine the onset of an apnea episode. In the preferred embodiment, this is a microphone or motion sensor which generates an electrical signal corresponding to the presence of breath or snoring sounds. Other sensors which may be used include an oximeter to measure the percentage of oxygen saturation of the blood, an airflow sensor, an airway resistance sensor, a strain gauge, or an impedance plethysmograph. Sensor 24 is fixedly mounted to main substrate 12 such that when collar 10 is

positioned using chin notch 18, sensor 24 is properly located for its monitoring function. Sensor 24 is electrically coupled to electronic module 20 using cable 30. Electronic module 20 contains the circuitry to process the sensor output and generate stimulation signals as required. Electronic module 20 is discussed in more detail below.

The electrical stimulation signals generated by electronic module 20 are coupled to electrode 26 and electrode 28 via cable 32 and cable 34, respectively. Electrodes 26 and 28 are similar to commercially available muscle stimulation electrodes. Each is fixed to main substrate 12 such that it will be properly located to stimulate the genioglossus and related muscle groups when collar 10 is in position.

FIG. 2 shows obstructive sleep apnea collar 11 employing a first alternative positioning means. Collar 11 has a color stripe 19 which the patient positions over his epiglottis. Collar 11 is constructed such that color stripe 19 is located the proper distance from hook 13 and latch 15.

FIG. 3 is a plan view of obstructive sleep apnea collar 21 using a second alternative positioning means. Collar 21 employs shoulder notches 27 and 29 which are spaced appropriately from hook 23 and latch 25. Unlike chin notch 18 (see also FIG. 1), shoulder notches 27 and 29 are located along the bottom surface of collar 21.

FIG. 4 is a frontal view of patient 100 with obstructive sleep apnea collar 10 properly positioned for treatment. All other components are as previously described.

FIG. 5 is a side view of patient 100 with obstructive sleep apnea collar 10 in position. Also shown is optional feedback positioning button 102. The use of button 102 provides patient 100 with positive verification that collar 10 has been properly positioned. Button 102 is depressed by patient 100 to activate the muscle stimulation signal from electronic module 20. If collar 10 is properly positioned, patient 100 will notice a contraction of the muscles associated with his upper air passageway.

FIG. 6 is a schematic view of electronic module 20 showing its major components. Electronic circuit 200 is powered by primary battery 104 which may or may not be included in the collar. Electronic circuit 200 is preferably a custom integrated circuit, but more probably is a hybrid.

Electronic circuit 200 may or may not be included in the collar and has one input cable 30 from sensor 24 and two output cables 32 and 34 coupled to electrodes 26 and 28, respectively (see also FIG. 1). Referring again to FIG. 6, input cable 30 terminates at terminals 112 and 114. Similarly, output cable 32 terminates at terminal 108 and output cable 34 terminates at terminal 110.

FIG. 7 is a block diagram of electronic circuit 200. Each of the components of electronic circuit 200 is readily available in commercial form. Cable 30 from sensor 24 (see also FIGS. 1 and 6), transfers the sensor signal via terminals 112 and 114 to In amp 202, which provides initial amplification. Bandpass filter 204 filters the amplified sensor signal to obtain the desired pass band. For sensor 24 as a breath or snoring activity sensor, for example, the desired passband of bandpass filter 204 is approximately from 20 to 200 hertz.

The filtered signal is presented to full wave rectifier 205 and then to integrator 206 which integrates the signal over the appropriate time. For sensor 24 as an audio sensor, one-third of a second is an appropriate integration time as determined by reset timer 211. The output of integrator 206 is a level representing the integrated sensor signal. This level is presented to threshold detector 207 having the threshold value set by threshold adjust 216. This ensures that whenever the integrated level exceeds the threshold set by threshold adjust 216, a signal is set to on-time timer 208 which initiates a ramp signal from ramp generator 209 for the duration as set by trigger adjust 212.

Stimulation signals are produced by pulse generator 210 having an amplitude set by the output of ramp generator 209. The amplitude of these pulses is set by amplitude adjust 213. The on-set of these pulses is slowly ramped up in amplitude by ramp

generator 209. These signals are appropriate to stimulate contraction of the genioglossus and related muscle groups. The preferred stimulation frequency is 30 to 60 pulses per second. On-time timer 208 ensures that the stimulation bursts are at least a predetermined minimum duration. As explained above, button 102 is a single pole/single throw push button used to manually activate pulse generator 210. This manual activation permits patient 100 to verify proper positioning of collar 10.

The output of pulse generator 210 is coupled to step-up transformer 214 which provides the appropriate voltage necessary to drive electrodes 26 and 28 via cables 32 and 34, respectively.

Having thus described the preferred embodiments of the present invention, those of skill in the art will be readily able to apply the teachings found herein to yet other embodiments without departing from the scope of the claims hereto attached.

WE CLAIM:

1. An apparatus for treating obstruction of an upper air passageway of a patient comprising:

a. means for sensing the onset of an obstructive sleep apnea episode;

b. means coupled to said sensing means for generating muscle stimulating signals;

c. electrode means coupled to said generating means for transcutaneously transferring said muscle stimulating signals to clear said upper air passageway of said patient; and

d. means attached to said sensing means, said generating means, and said electrode means for maintaining said sensing means, said generating means, and said electrode means in proximity with said patient.

2. An apparatus according to claim 1 further comprising means coupled to said maintaining means for positioning said maintaining means with respect to said patient.

3. An apparatus according to claim 2 wherein said maintaining means further comprises a collar.

4. An apparatus according to claim 3 wherein said sensing means further comprises an audio sensor.

5. An apparatus according to claim 3 wherein said sensing means further comprises an activity sensor.

6. An apparatus according to claim 3 wherein said sensing means further comprises an oximeter.

7. An apparatus according to claim 3 wherein said sensing means further comprises an air flowmeter.

8. An apparatus according to claims 2, 3, 4, 5, 6, or 7 wherein said positioning means further comprises a unique shape.

9. An apparatus according to claims 2, 3, 4, 5, 6, or 7 wherein said positioning means further comprises a unique color.

10. An apparatus according to claim 8 wherein said unique shape further comprises a chin notch.

11. An apparatus according to claim 8 wherein said unique shape further comprises at least one shoulder notch.

12. An apparatus according to claim 8 further comprising means coupled to said generating means for verifying proper placement of said maintaining means.

13. An apparatus according to claim 9 further comprising means coupled to said generating means for verifying proper placement of said maintaining means.

14. An apparatus according to claim 10 further comprising means coupled to said generating means for verifying proper placement of said maintaining means.

15. An apparatus according to claim 11 further comprising means coupled to said generating means for verifying proper placement of said maintaining means.

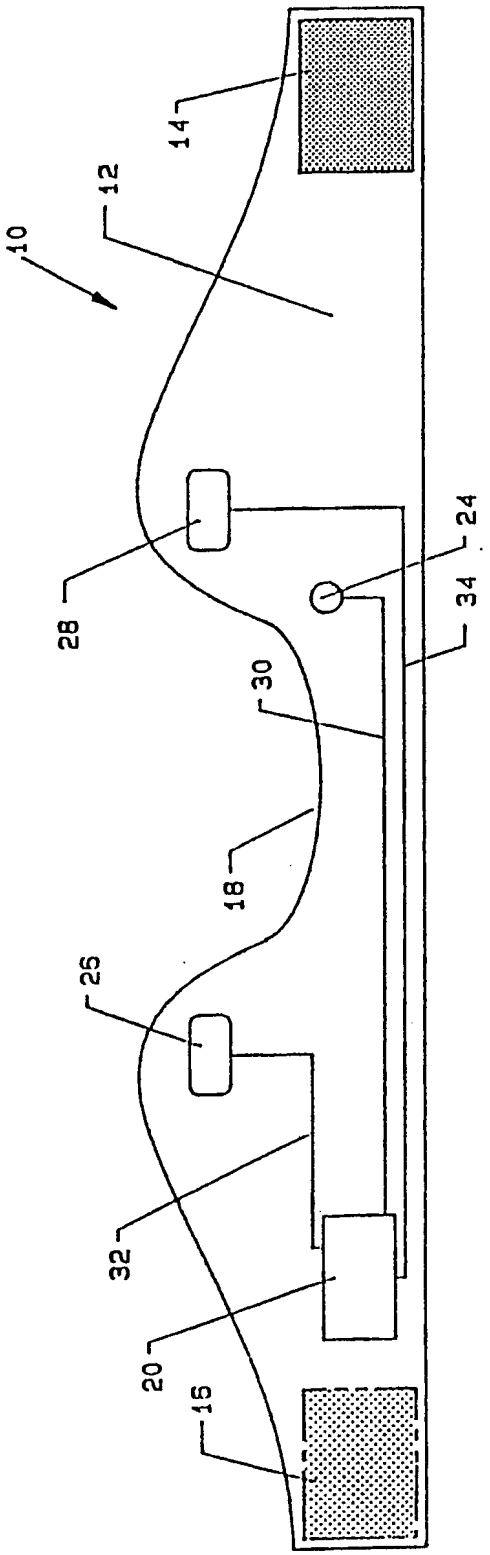

FIG.1

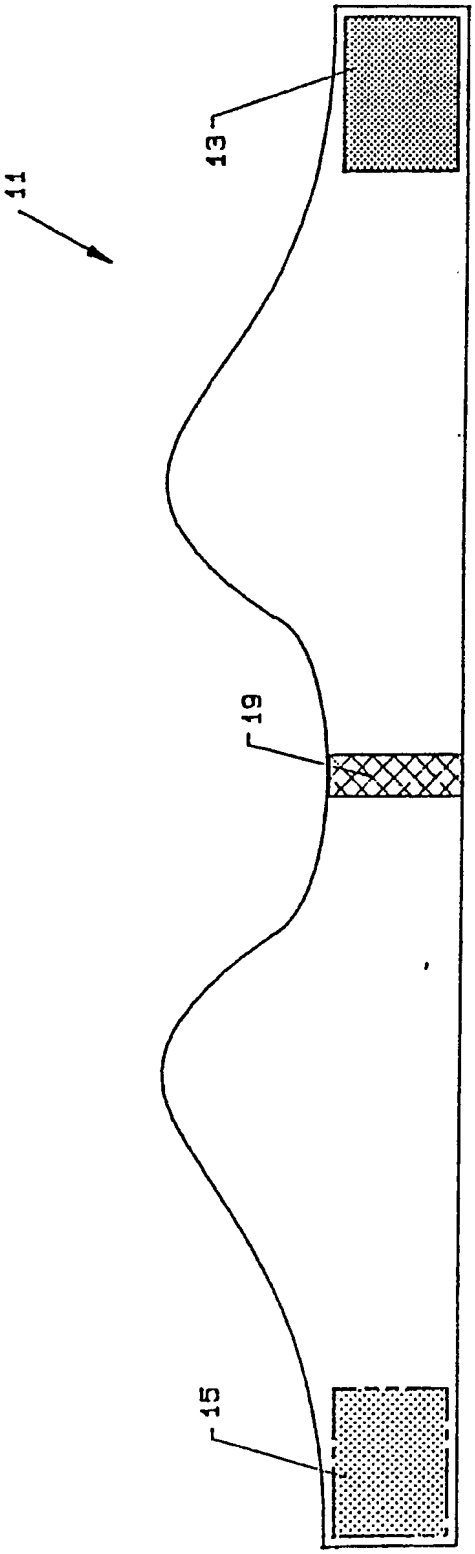

FIG. 2

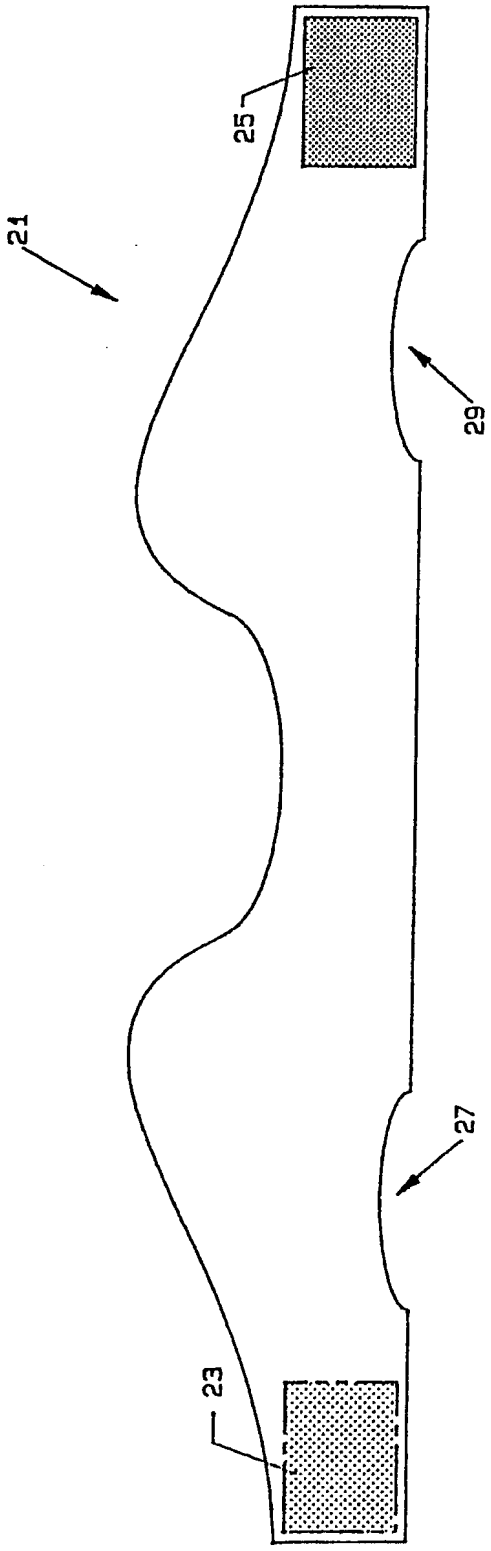

FIG. 3

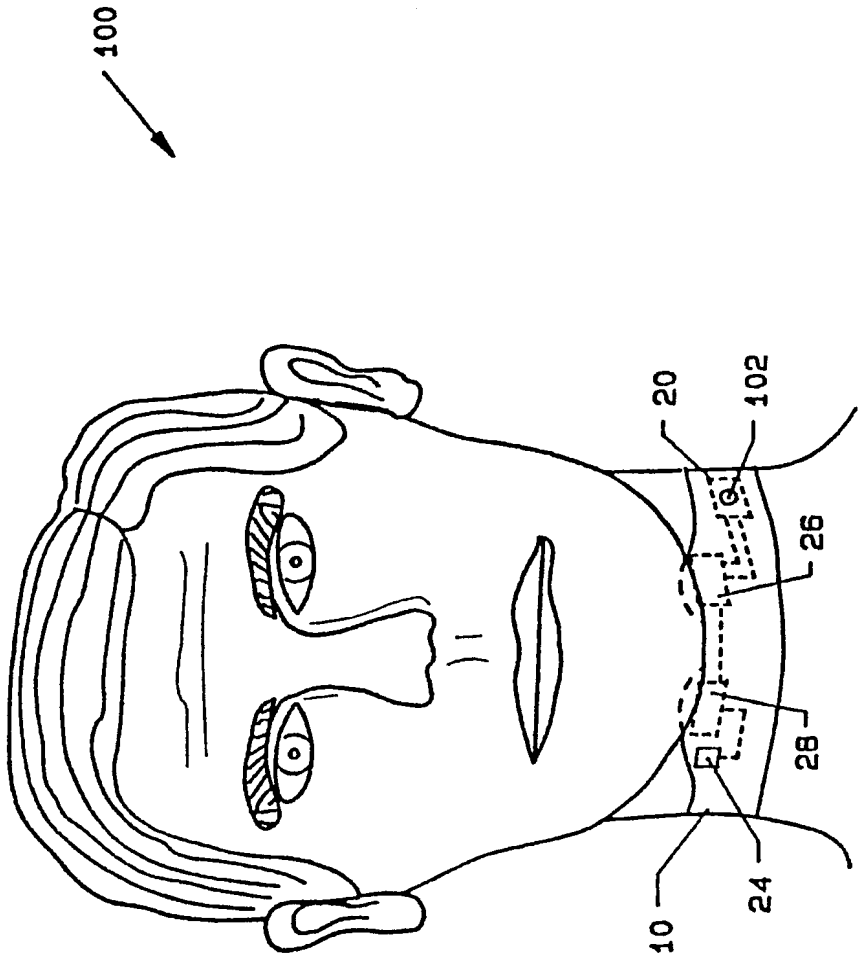

FIG. 4

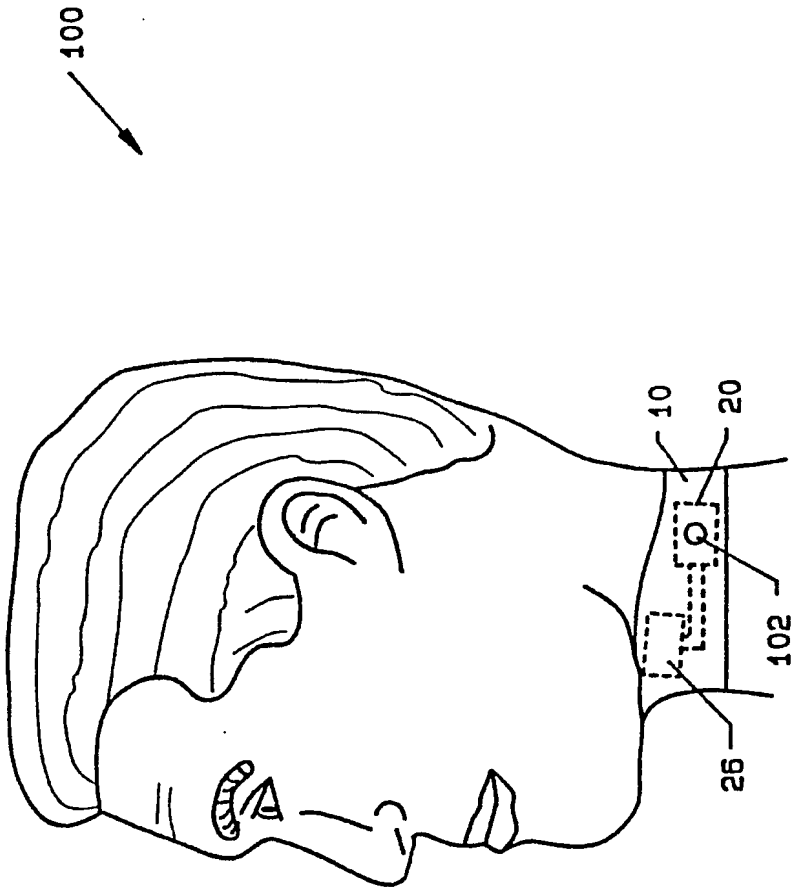

FIG. 5

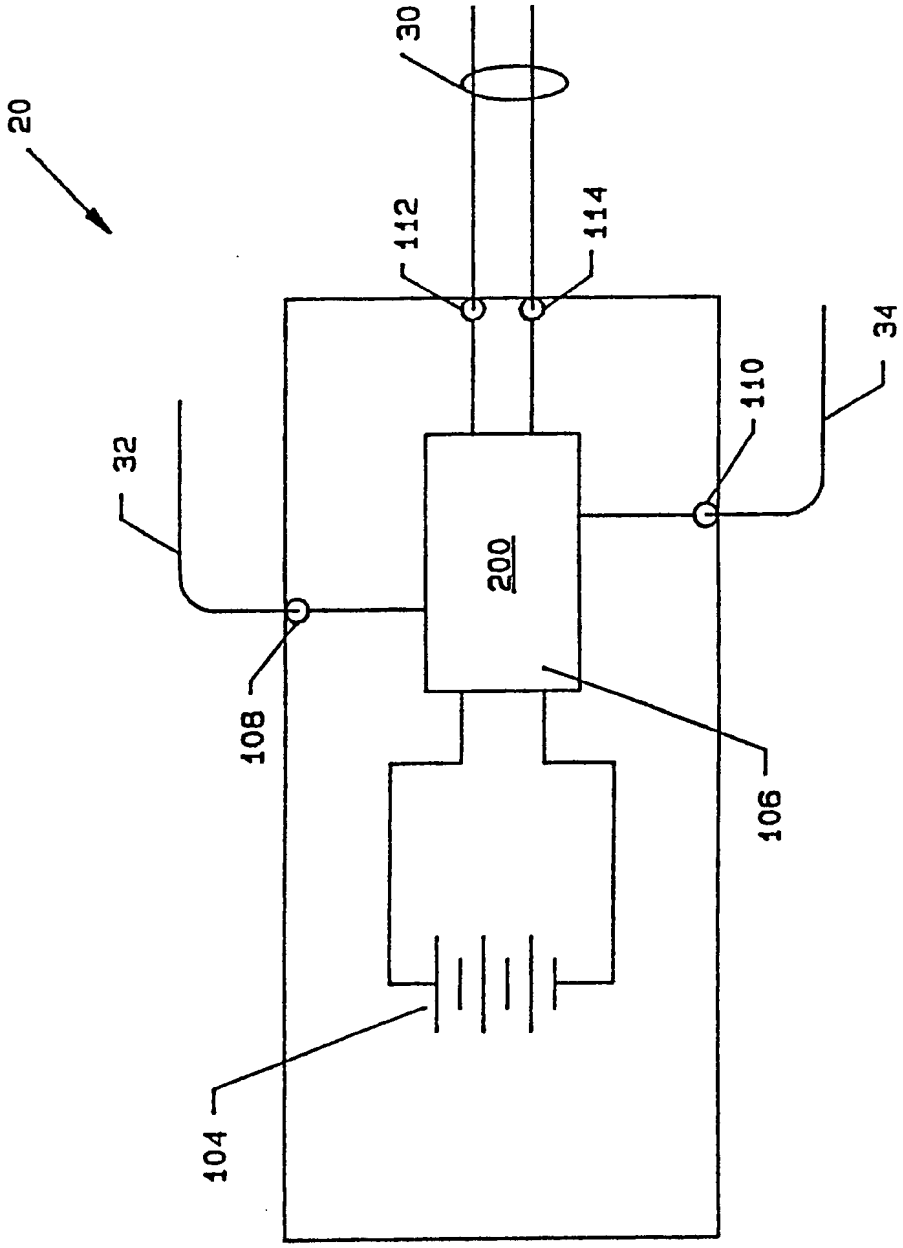

FIG. 6

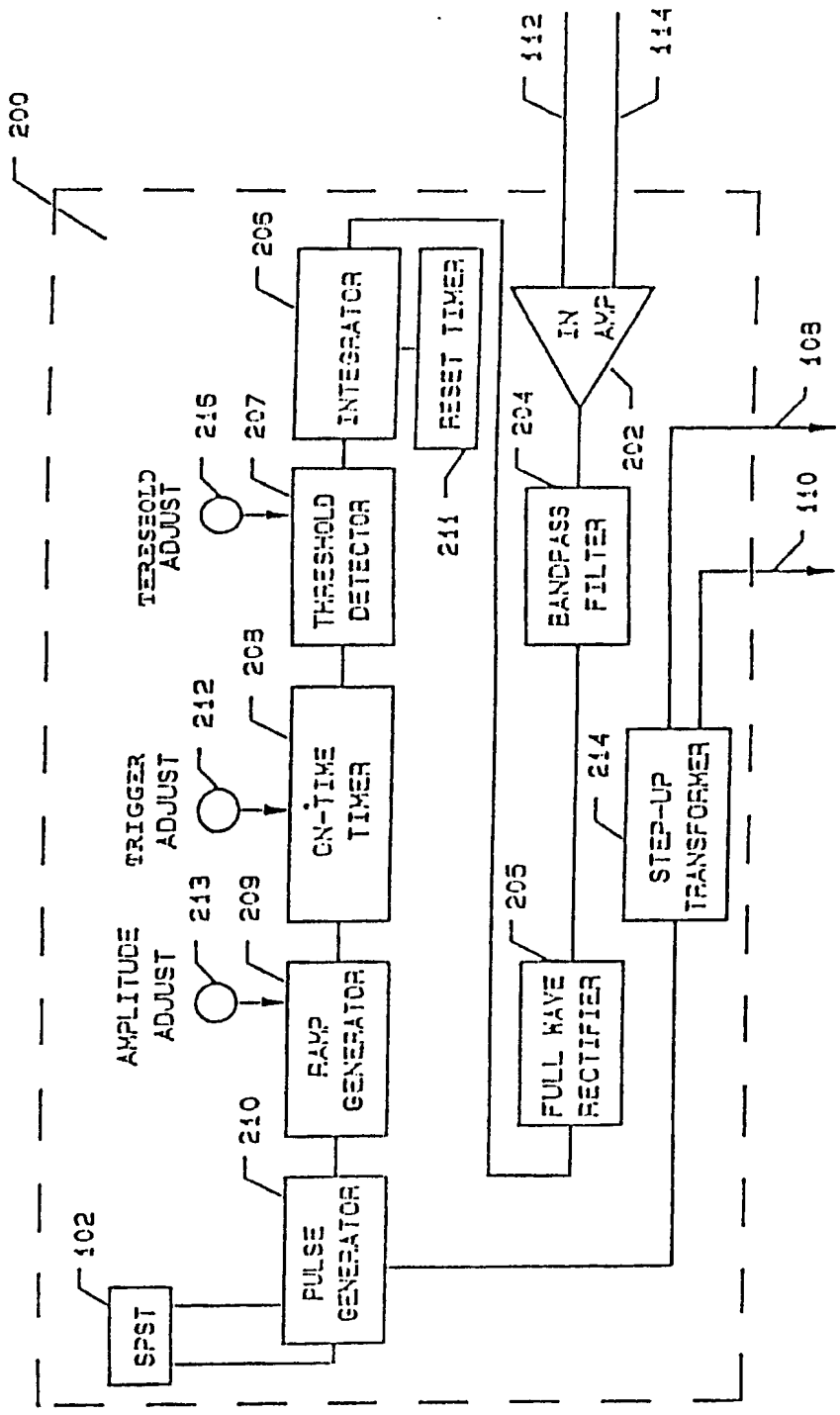
200
102
SPST
PULSE GENERATOR
210
RAMP GENERATOR
209
AMPLITUDE ADJUST
213
ON-TIME TIMER
208
TRIGGER ADJUST
212
THRESHOLD DETECTOR
207
THRESHOLD ADJUST
215
INTEGRATOR
206
RESET TIMER
211
FULL WAVE RECTIFIER
205
BANDPASS FILTER
204
IN AMP
202
STEP-UP TRANSFORMER
214
112
114
108
110

FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/05820

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5): A61C 5/14
U.S. CL: 121/859

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S. CL:	128/846,848,859,860,724,733,773,774,777; 340/573,575,626,665,668

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X / Y	US, A, 4,715,367 (CROSSLEY) 29 December 1987. See the entire document.	1-5, 7-8 / 9
A	US, A, 3,480,010 (CROSSLEY) 25 November 1969. See the entire document.	1-15
A	US, A, 4,440,160 (FISCHELL ET AL.) 03 April 1984. See the entire document.	1-15
A	US, A, 4,220,142 (ROSEN ET AL.) 02 September 1980. See the entire document.	1-15
A	US, A, 3,998,209 (MACVAUGH) 21 December 1976. See the entire document.	1-15
A	US, A, 4,669,477 (OBER) 02 June 1987 See the entire document.	1-15

* Special categories of cited documents: [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
13 SEPTEMBER 1991	17 OCT 1991
International Searching Authority	**Signature of Authorized Officer**
ISA/US	MICHAEL A. BROWN